APPLICATION NUMBER ATTY. DOCKET NO. **SUBSTITUTE FORM PTO-1449** Not yet assigned U.S. DEPARTMENT OF COMMERCE 09403-0003 DI1 U.S. PATENT AND TRADEMARK OFFICE FIRST NAMED INVENTOR **INFÓRMATION DISCLOSURE** Ajay GUPTA STATEMENT BY APPLICANT 1616 FILING DATE ART UNIT Not yet assigned-HEREWITH

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U.S. PATENT DOCUMENTS

| | AMINER TIALS | Cite No. | DOCUMENT NUMBER Number-Kind Code (if known) | PUBLICATION DATE (MM/DD/YYYY) | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT | PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR |
|---|-----------------|-------------|--|----------------------------------|--|---|
| 4 | X | A | 3,911,915 | 10/74 | Seifter et al. | |
| | 7 | В | 4,315,942 | 02/82 | Corden | |
| | - | С | 4,756,838 | 07/88 | Veltman | |
| | ÷ | D | 5,108,767 | 04/92 | Mulchandani et al. | |
| | | E | 5,393,777 | 02/95 | Crosa | |
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| 5 | | U | 4,867,963 | 09/89 | Maurer et al. | |

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|----------------------|--|--|---|--|
| A | н | Sunder-Plassmann et al., Nephrol Dial Transplant, 11:1797-1802 (1996). | | |
| , | I | Rubinger et al., Amer. J. Kidney Diseases, VII No. 2:125-129 (1986). | | |
| | J. | Zanen et al., Nephrol Dial Transplant, 11:820-824 (1996). | | |
| | К | The Merck Index, Merck and Co., Inc., Rahway, NJ, Budavari Ed., 11 th Edition:3969 (1989). | | |
| | L | Dorland's Illustrated Medical Dictionary, WB Saunders Co., 27 th Edition:462,741,837,1541 (1985). | | |
| | М | Berner et al., J. Nutr., 115:1042-1049 (1985). | | |
| | N | Hazell et al., Br. J. Nutr., 39:631-639 (1978). | | |
| | 0 | Basta, et al., Iron deficiency anemia and the productivity of adult males in Indonesia, Am. J. Clin. Nutr., 32:916 (1979). | | |
| | P | Brown et al., Intravenously administered saccharated iron oxide in the treatment of hypochromic anemia, JAMA, 144:1084-1089 (1950). | | |
| A | Q | Calvar et al., Intravenous administration of iron gluconate during hemodialysis, Iron Research, New York: Plenum Press, 1994:219-228. | | |
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| | R | Cook et al., Iron deficiency: The global C. Ed. Progress in Iron Research, New Yor 1994:219-228. | | |
| | S | Drueke et al., Iron defeciency and erythmia: developing the optimum treatment so Report, The Oxford Forum, Worcester, Co. Oxford, Magdalen Centre, The Oxford Scientific Co. | trategy, In: Highlights llege, Oxford, 1996. CBC | |
| | Т | Fishbane et al., The safety of intravend Hemodialysis Patients, Am. J. Kidney Dia | | |
| | U | Lieberman et al., Association of matern premature labor, Am. J. Obstet. Cynecol | | |
| | V | Lozoff et al., Long-term developmental iron deficiency, N. Engl. J. Med., 325: | | |
| | W | NKF-DOQI clinical practical guidelines of chronic renal failure, Am. J. Kid. D | | |
| · | х | Ohira et al., Work capacity, heart rate responses to iron treatment, Br. J. Hae | | |
| | Y | Oski et al., The effects of therapy on iron-deficient infants, Pediatrics, 71: | _ | |
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|-------------------|--|--|---|
| Q | z | Oski et al., Effect of iron therapy on behavior performance in nonanemic, iron-deficient infants, Pediatrics, 71:877 (1983). | |
| | AA | Schultink et al., Low compliance with an iron-supplementation program: a study among pregnant women in Jakarta, Indonesia, Am.J. Cliin. Nutr., 32:916 (1979). | |
| | AB | Stockman, The treatment of chlorosis by iron and some other drugs, Br. Med. J., I:881-885 (1983). | |
| | AC | Yoshifumi Tsuji et al., Effect of recombinant human erythropoietin or anamia after gastectomy, Eur. J. Surg., 161:29-33 (1995). | |
| | AD | Shimamatsu, Experience with i.v. iron chondroitin-sulphate colloid in Japanese haemodialysis patients, Nephrol Dial Transplant, 13:1053 (1998). | |
| | AE | The National Formulary VII, 165 (1942). | |
| | AF | Dainippon Pharmaceutical product description for BLUTAL Injection, 175-177 (1994). | |
| | AG | Erslev, Drug Therapy, N. Engl. J. Med., 324 (19):1339-1344 (1991). | |
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|-------------------|----------------|--|---|
| a | AH | Moore et al., Incidence, causes, and treatment of iron deficiency anemia in hemodialysis patients, <u>J. Renal. Nutrition</u> , 2:105-112 (1992). | |
| | AI | Kleiner et al., The role of iron and other factors in patients unresponsive to erytropoietin therapy, Seminars in Dialysis, 8:(1):29-34 (1995). | |
| | ĄJ | Konopka et al., Iron transfer from transferrin ot ferritin mediated by polyphosphate compounds, <u>Biochem. Biophys. Acta.</u> , 677:417-423 (1981). | |
| | AK | Konopka et al., Iron transfer from transferrin ot ferritin mediated by polyphosphate compounds, Biochem. Biophys. Acta., 96(3):1408-1413 (1980). | |
| | AL | Morgan, Iron exchange between transferrin molecules mediated by phosphate compounds and other cell metabolites, <u>Biochem. Biophys.</u> Acta., 499(1):169-177 (1977). | |
| | AM | Kolff, First clinical experience with artificial kidney, Ann. Intern. Med., 62:608 (1965). | |
| | AN | Scribner et al., The treatment of chronic uremia by means of intermittent hemodialysis; a preliminary report, <u>Trans. Amer. Soc.</u> Artif. Int. Organs., 6:114 (1960). | |
| IS | AO | Jacobs et al., Isolation and characterization of genomic and cDNA clones of human erythropoietin, Nature, 313:806-810 (1985), | |
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|----------------------|---------------|--|---|
| al | АР | Levin, The impact of epoetin alfa: quality of life and hematocrit level, Am. J. Kid. Dis., XX (Su;;1. 1 (July):16-20 (1992). | |
| | AQ | Eschbach et al., Iron balance in hemodialysis patients, Ann. Intern. Med., 87:710-713 (1977). | |
| | AR | Woorwood, Blood Rev., 4:259-269 (1980). | |
| | AS | Macdougall et al., Detection of functional iron deficiency during erythropoietin treatment: a new approach, Br. Med. J. , 304:225-226 (1992). | |
| : | AT | Van Wyck et al., Iron status in patients reciving erythropoietin for dialysis-associated anemia, Kidney Int., 35:712-716 (1989). | |
| | AU | Wingard et al., Efficacy of oral iron therapy inpatients receiving recombinant human erythropoietin, Am. J. Kid. Dis., 25:433-439 (1995). | |
| | AV | MacDougall et al., Poor response to the treatment of renal anaemia with erythropoietin corrected iron, Br. Med. J., 299:157-158 (1989). | |
| |) AW | Schaeffer and Schaefer, The hypochromic red cell: a new parameter for monitoring or iron supplementation, J. Perinat. Med., 23:83-88 (1995) | |
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|----------------------|-------------|--|---|
| al | Ах | Horl, How to diagnose and correct iron deficiency during r-huEPO therapy-a consensus report, Nephrol. Dial. Transplant., 11:246-250 (1996). | |
| | AY | Sepandj et al., Econommic appraisal of maintenance parenteral iron administration in treatment of anaemia in chronic, Nephrol. Dial. Transplant., 11:319-322 (1996). | |
| | AZ | Rosenlof et al., Iron availability is transiently improved by intravenous iron medication in patients, Clin. Nephrol. , 43:249-255 (1995). | |
| | ва | Fishbane and Lynn, The utility of zinc protoporphyrin for predicting the need for intravenous iron therapy, Am. J. Kidney Dis., 25:426-432 (1995). | |
| | BB | Macdougall et al., A randomized controlled study of iron supplementation in patients treated with erythropoietin, J. Amer. Soc. Nephrol., 4:428 (abstract) (1993). | |
| | вс | Sunder-Plassmann and Horl., Importance of iron supply for erythropoietin therapy, Nephrol. Dial. Transplant., 10:2070-2076 (1995). | |
| | BD | Schaeffer and Schaeffer, Management of iron substitution therapy during r-HuEPO therapy in chronic renal failure patients, <u>Erythropoiesis</u> , 3:71-75 (1992). | |
| al | BE | Nyvad et al., Intravenous iron-sucrose complex to reduce epoetin demand in dialysis patients, <u>Lancet</u> , 344:1305-1306 (1994). | |
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|--|--|--|---|--|
| | BD | Hamstra et al., Intravenous iron dextran in clinical medicine, JAMA, 243:1726-1731 (1980). | | |
| | BE | Kumpf and Holland, Parenteral iron dextran therapy, <u>DICP Ann</u> Pharmacother, 24:162-166 (1990). | | |
| | BF | Weinberg, Iron withholding: a defense against infection and neoplasia, Physiol. Rev., 64-65-102 (1984). | | |
| | BG | Heath et al., Quantitative aspects of iron deficiency in hypochromic anemia, J. Clin. Invest., 11:1293 (1932). | | |
| | ВН | Best and Taylor, The Physiological Basis of Medical Practice, The Williams & Wilkins Co., Baltimore, MD pp. 94-99 (1943). | | |
| | BI | Nissim, Intravenous administration of iron, Lancet , 2:49-51 (1947). | | |
| | BJ | Goetsch et al., Observations on the effect of massive doses of iron given intravenously to patients with hypochromic anemia (1946). | | |
| | вк | Cox et al., Valency investigations of iron dextran ('Imferon'), Nature, 207:1202-1203 (1965). | | |
| | BL | Goldberg, In <u>Iron in Clinical Medicine</u> , eds. Wallerstein, Ro Mettier, SR. Berkeley; Univ. of California Press, Vol. 78 (1958). | | |
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|---|----------|--|---|
| W | вм | Hatton et al., Removal of iron dextran by hemodialysis: as in vitro study, Am. J. Kid. Dis., 26(2):327-330 (1995). | |
| | BN | Pascual et al., Intravenous Fe-Gluconate-Na for iron-deficient patients on hemodialysis, Nephron, 60:121 (1992). | |
| | во | Allegra et al., Iron deficiency in maintenance hemodialysis patients: assessment of diagnosis criteria, Nephron, 57:175-182 (1991). | |
| | ВР | Pollack and Weaver, Guinea pig and human red cell hemolysates release iron from transferrin, <u>J. Lab. Clin. Med.</u> , 105(5):629-634 (1985). | |
| | BQ | Pollack et al., Iron removal from transferrin. An experimental study., Biochim. Biophys. Acta., 497(2):481-487 (1977). | |
| | BR | Morgan, Studies on the mechanism of iron release from transferrin, Biochim. Biophys. Acta., 580(2):312-326 (1979). | |
| a | BS | Carver and Frieden, Factors affecting the adenosine triphosphate induced release of iron from transferrin, Biochemistry, 17(1):167-172 (1978). | |
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|-------------------|--|-------------|--|---|
| 6 | P | BT | Nilsen and Romslo, Phrophosphate as a ligand for delivery of iron to isolated rat-liver mitochondria, Biochim. Biophys. Acta., 766(1):233-239 (1984). | |
| | | BU | Javiad et al., Interactions between infections, malnutrition and iron nutritional status in Pakistani infants, Acta. Paeditrica Scandinavica - Supplement, 374:141-50 (1991). | |
| | | BV | Byrd and Horwitz, Lactoferrin inhibits or promotes Legionella pneumopilla intracellular multiplication, <u>J. Clin. Invest.</u> , 88(4):1103-1112 (1991). | |
| · | - | BW | Ristroph et al., Chemically defined medium for Legionella pneumphila growth, J. Clin. Microbiology, 13(1):115-119 (1981). | |
| | | вх | Feeley et al., Primary isolation media for Legionnaires disease bacterium, Journal of Clinical Microbiology, 8(3):320-5 (1978). | |
| | | вч | Maurer et al., Paramagnetic pyrophosphate. Preliminary studies on magnetic resonance contrast enhancement of acute myocardial, Investigative Radiology, 25(2):153-63 (1990). | |
| W | 9 | BZ | Stevenson et al., The toxicity of Sn-pyrophosphate: clinical manifestations prior to acute LD50, J. Nucl. Med., 15:252-256 (1974). | |
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|----------------------|-----------------|--|---|
| as a | CA | Harkem et al., Early ischemia after complete coronary ligation in the rabbit, dog, pig and monkey, Am. J. Physiol., 241:H202 (1981). | |
| | СВ | Sillen and Martell, Stability constants of metal-ion complexes, The Chemical Society, London, (select pages only)(1964). | |
| | CD | Kornberg, On the metabolic significance of phosphoroltyic and pyrophosphorolytic reactions, In Kasha M, Pullman B, eds. <u>Horizons</u> on Biochemistry, New York, Academic Press, pp. 251-264 (1962). | |
| | CE | Jung et al., The fate of intravenously injected 32-p-pyrophosphate in dogs, Amer. J. Physiol., 218:1757 (1970). | |
| | CF | Fleisch and Bisaz, Mechanism of calcification: inhibitory role of pyrophosphate, Nature (Lond.), 195:911 (1962). | |
| | CG | Fleisch, in Fleisch H, ed., <u>Bisphosphanates in bone disease</u> : from the laboratory to the patient, 2 nd ed. Carnforth, Lancs, England: The Parthenon Publishing Group Ltd., pp. 31-33 (1995). | |
| QQ | СН | U.S. Renal Data System, USRDS 1995 Annual Data Report., The National Institutes of Health, National Institue of Diabetes and digestive and Kidney Diseases, Bethdsda, MD (1995). | |
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|--------------------|----------------|---|---|
| W | СІ | Ifudo et al., The intensity of hemodialysis and the response to rerythropoietin in patients with end stage renal disease, N. Engl. J. Med., 334:420-425 (1996). | |
| | CJ | Cheuk et al., Kinetics of pyrophosphate induced iron release from fiferric ovotranferrin, <u>J. of Inorganic Biochemistry</u> , 29:301-311 (1987). | |
| | CK | Fishbane et al., Reduction in recombinant human erythropoietin doses by the use of chronic intravenous iron supplementation, Am. J. Kidney Diseases, 26:41-46 (1995). | |
| | CL | Hurrett et al., Iron fortification of infant cerals: a proposal for the use of ferrous fumarate, Am. J. Clin. Nutr., 49:1274-82 (1989). | |
| | СМ | Moore, An outline of iron metabolism, pp. 5-7 (only information available). | |
| | CN | Nilsen, Effects pf calcium on hepatocyte iron uptake from tranferrin iron-pyrophosphate and iron-ascorbate. (only information available; best copy). | |
| | СО | Schibler, Inhibition by pyrophosphate and poly-phosphate of aortic calcification induced by vitamin D, in rats, <u>J. Clin. Sci.</u> , 35:363-372 (1968). | |
| | CP | Tsuji et al., <u>Eur. J. Surg.</u> 161:29-33 (1995) | |
| af |)co | Starkenstein, E., Beitrage zur Pharmakologie des Eisens., Archiv fur experiment, Path. u. Pharmakol. 118:131-191 (1921) | |
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